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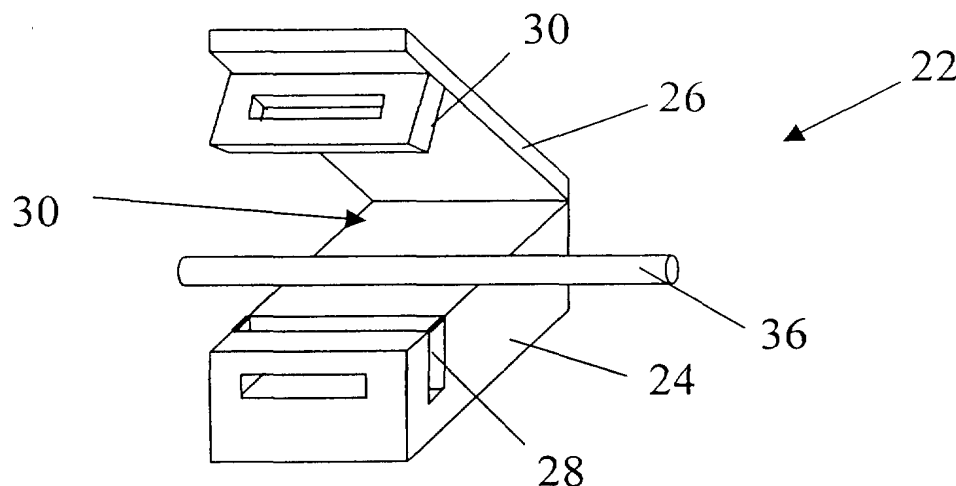
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- (71) Applicant (*for all designated States except US*): **CYCLO MEDICS LTD.** [IL/IL]; P.O. Box 3854, 31037 Haifa (IL).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **SEGAL, Baruch** [IL/IL]; Hageula Street 12/7, 45272 Hod Hasharon (IL). **RADOMSKI, Ronen** [IL/IL]; Oren Street 9, 34731 Haifa (IL). **AMISAR, Shai** [IL/IL]; Shmuel Klein Street 1, 93101 Jerusalem (IL).
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(54) Title: METHOD OF SAFE INFUSION



(57) Abstract: A lock-and-key apparatus for use with an infusion-bag administration system, the apparatus including proximal and distal sides with respect to a user, first and second blocks arranged to be selectably joined and selectably locked together and having a first common interface between them when they are joined, and a lock-and-key mechanism. The lock-and-key mechanism includes a lock, in communication with the first and second blocks, for selectably locking them together and a key, located with the patient to whom an infusion is intended, for unlocking the lock. When a resilient portion of the infusion-bag administration system is arranged between the first and second blocks, on the first interface, the locking of the first and second blocks together will prevent passage of the infusion liquid.



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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## METHOD OF SAFE INFUSION

### FIELD OF THE INVENTION

The present invention relates generally to an apparatus and a method for safe infusion, and in particular to lock-and-key apparatus and a method for ensuring that an infusion is administered to a patient for whom it is intended.

### BACKGROUND OF THE INVENTION

Blood infusion is a process of infusing blood products into a patient to raise the concentration of red blood cells. It is used in cases of trauma, excessive bleeding, surgery, or other open injuries. Properly administered, blood infusion will save lives. But when a wrong blood type is administered to a patient, it will cause a reaction that may result in death.

Prior to infusion, a patient's blood is sampled, in order to be typed (A, B, O or AB) and cross matched (mixed together to see if its compatible).

Regulations by the Israeli Ministry of Health set the following requirements for taking a blood sample:

1. the patient from whom blood is sampled must wear an identity band, for example on his wrist, containing his identity details: name, identity number, and preferably a bar code;
2. sampling must be performed by a fully qualified medical doctor, holding a current license;
3. a test tube and a blood-order form must be prepared, prior to sampling, by marking them with a sticker containing the patient's identity details, stamping the sticker with a seal, and signing the sticker by the doctor performing the blood sampling; and
4. the doctor must perform the following steps:
  - approach the patient (who may be unconscious, or otherwise unable to communicate);
  - read the patient's identity details from his identity band;
  - compare the identity details with those on the test-tube and on the blood-order form; and
  - draw a blood sample into the marked test tube.

For the purpose of ordering blood from the blood bank, the blood-order form, marked with a sticker containing the patient's identity details, and stamped with a seal containing the doctor's signature, is sent to the blood bank. The blood-order form includes stickers of the

patient's identity details, in the same number as the number of units of blood that are ordered.

At the blood bank, after the blood is typed and cross matched, the proper blood is supplied, in bags of blood units, to the hospital ward where the patient is located. The blood units are accompanied by blood-bank forms, prepared at the blood bank, and also containing stickers of the patient's identity details.

Furthermore, regulations by the Israeli Ministry of Health set forth (or prescribed) the following protocol for blood infusion at the hospital ward:

1. the blood units are prepared by nurses;
2. prior to infusion, the patient must be identified by at least two people, a medical doctor and a nurse, at the patient's bed side, by the patient's identity band;
3. the doctor and the nurse must examine and compare the patient's identity details, as marked on the blood units, with those on the blood-bank form, and those on the patient's identity band, at the patient's bed side;
4. the doctor must sign the label on the blood unit and add his personal details to his signature;
5. the blood units are then administered to the patient; and
6. the empty blood-unit bags must remain in the hospital ward for 6 hours, for follow-up.

The protocol for blood infusion at the hospital ward clearly defines the responsibilities of each party involved in blood infusion, the doctor, the nurse and the blood bank, as follows:

It is the responsibilities of the doctor to:

1. sample the blood and forward the blood sample to the blood bank;
2. identify the blood unit from the blood bank, at the patient's bedside; and
3. identify the patient for blood infusion, at the patient's bedside, by the patient's identity band.

It is the responsibility of the nurse to:

1. prepare the blood unit for infusion;
  2. identify the blood unit from the blood bank, with the doctor, at the patient's bedside;
- and
3. administer the blood infusion.

It is the responsibility of the blood bank to:

1. receive the blood sample;
2. type and cross match the blood;
3. prepare the blood units in accordance with the blood order; and

4. send the blood units to the hospital ward where the patient is located.

By law, since no medical knowledge is required for identifying a patient by reading his personal details, infusion of wrong blood is not considered malpractice; rather, it is a criminal offense, and if the patient dies from it, it is considered manslaughter. Therefore, the responsible doctor may face a charge of manslaughter as well as a civil suit. In addition, he may lose his medical license and his place of work. Similarly, the hospital may be faced with a civil suit for damages, and the insurance company may be required to pay the damages.

It is therefore desirable to devise a system of safe blood infusion that will further protect the patient and the doctor from a likelihood of an infusion of wrong blood.

### SUMMARY OF THE INVENTION

It is an aim of the present invention to provide lock-and-key apparatus and a method for ensuring that an infusion is administered to a patient for whom it is intended.

There is thus provided, in accordance with the present invention, lock-and-key apparatus for use with an infusion-bag administration system, in which the lock-and-key apparatus includes proximal and distal sides with respect to a user; first and second blocks, arranged to be selectably joined and selectably locked together, and having a first common interface between them, when they are joined; and a lock-and-key mechanism which includes:

a lock, in communication with the first and second blocks, for selectably locking them together; and

a key, located with the patient to whom the infusion is intended, for unlocking the lock, wherein, when a resilient portion of the infusion-bag administration system is arranged between the first and second blocks, on the first interface, the locking of the first and second blocks together will prevent passage of the infusion liquid.

Additionally, in accordance with the present invention, the first and second blocks are physically attached to one another with at least one hinge.

Furthermore, in accordance with the present invention, the lock includes a first plate having distal and proximal ends, with respect to a user, and side edges; and a recessed portion, arranged on the first plate at predetermined distances from the distal end and side edges,

and the key includes a second plate substantially of a same width as the first plate, but of greater length, and also having distal and proximal ends, and side edges; and a protrusion, arranged on the second plate at substantially the same predetermined distances from the distal

end and side edges, as those of the recessed portion of the first plate, so as to be superimposed on the recessed portion, wherein

the predetermined distances of the recessed portion and protrusion from the distal end and side edges are unique to each lock and key, so that only a key associated with it may be superimposed on a lock,

the second block includes a bar, protruding from it and arranged to cover a side of the first block, when the first and second blocks are joined, and further including a slot which penetrates fully through the bar of the second block and partly through the first block, from the proximal side,

when the first and second blocks are joined together and the first plate is fully inserted into the slot, the first and second blocks are locked together, and

the second plate, which is of greater length than the first plate, is partially inserted into the slot, locking its protrusion against the recessed portion of the first plate, and dragging the first plate out of the slot, the first and second blocks are unlocked.

Additionally, in accordance with the present invention, the recessed portion is a through hole.

Furthermore, in accordance with the present invention, the protrusion is shaped as a hook.

Alternatively, the first block further includes a channel, open towards the first common interface, and dividing the first block to a first, proximal portion and a second, distal portion,

wherein the bar, protruding from the second block, is further arranged to be inserted into the channel, thus forming second and third common interfaces between the first and second blocks,

and wherein the slot penetrates from the proximal side of the apparatus, completely through the first, proximal portion of the first block, the second common interface, the bar of the second block, the third common interface, and partly penetrates through the second, distal portion of the first block.

Additionally, in accordance with the present invention, the first and second plates are disposable.

In accordance with a preferred embodiment of the invention, the lock is electronically controlled, and the key includes patient's signal information,

wherein the apparatus further includes:

a signal reader for reading the patient's signal information; and

a processing unit, in communication with the signal reader and with the lock, for processing the patient's signal information from the signal reader and for selectably opening the lock based on the patient's signal information.

Additionally, in accordance with a preferred embodiment of the present invention, the key further includes signal information of a medical doctor and of a nurse who are administering the infusion.

Furthermore, in accordance with a preferred embodiment of the present invention, the patient's signal information is a bar code, physically attached to his person, wherein the signal reader is a bar-code scanner, arranged to read the bar code.

Alternatively, the patient's signal information is the patient's palm print, wherein the signal reader is a palm-print reader.

Alternatively, the patient's signal information is the patient's fingerprint, wherein the signal reader is a fingerprint reader.

Additionally, in accordance with a preferred embodiment of the present invention, the apparatus is physically hung from an infusion bag containing the infusion liquid for the patient, wherein when the apparatus is unlocked, the infusion liquid flows freely and can be administered to the patient.

In accordance with an embodiment of the invention, at least one of the first and second blocks is hollow, forming a cavity, wherein the infusion bag is contained in the cavity.

Additionally, in accordance with the present invention, the resilient portion of the infusion-bag administration system, through which the infusion liquid exits, is a resilient hose, connected to the infusion bag.

Alternatively, the resilient portion of the infusion-bag administration system, through which the infusion liquid exits, is an edge of the infusion bag.

Additionally, in accordance with a preferred embodiment of the present invention, the infusion liquid is blood.

There is thus also provided, in accordance with the present invention, a method for ensuring that an infusion is administered to a correct patient, which includes the following steps:

at the location where the infusion liquid is prepared, locking the infusion liquid with a lock, whose key is uniquely with the patient; and

by the patient, unlocking the infusion liquid with the patient's key.

Additionally, in accordance with the present invention, the step of locking includes locking with a physical lock, and the step of unlocking includes unlocking with a physical key.

In accordance with a preferred embodiment of the present invention, the step of locking includes locking electronically.

Additionally, in accordance with a preferred embodiment of the present invention, the step of unlocking includes unlocking electronically, which includes a step of reading in the patient's key, formed of the patient's signals.

Furthermore, in accordance with a preferred embodiment of the present invention, the step of reading in the patient's key, formed of the patient's signals, includes reading in a bar code, attached to the patient.

Alternatively, the step of reading in the patient's key, formed of the patient's signals, includes reading in the patient's palm print.

Alternatively, the step of reading in the patient's key, formed of the patient's signals, includes reading in the patient's fingerprints.

Additionally, in accordance with a preferred embodiment of the present invention, the step of reading in the patient's key, formed of the patient's signals, further includes reading in a doctor's signals and a nurse's signals, for indicating their presence, and for registering their identity.

Alternatively, the step of unlocking includes unlocking with an electromagnetic device.

Alternatively, in accordance with the present invention, the step of locking the infusion liquid with a lock further includes the steps of:

clamping the infusion liquid exit path with a clamp; and

locking the clamp, to prevent passage of the infusion liquid.

Alternatively, in accordance with the present invention, the step of locking the infusion liquid with a lock further includes the steps of placing the infusion liquid in a container; and locking the container.

There is thus also provided, in accordance with the present invention, a method for ensuring that a blood sample is marked correctly, which includes employing a bar-code scanner; scanning the bar code on the test tube into which the blood sample is to be drawn; scanning the bar code on the band of the patient from whom the blood sample is to be drawn; and verifying that the test-tube bar code and the patient's bar code are identical.



There is thus also provided, in accordance with the present invention, a method for ensuring that an infusion is administered to a correct patient, which includes the following steps:

- employing a bar-code scanner;
- scanning the bar code on the blood-unit bag;
- scanning the bar code on the band of the patient who is to receive the blood; and
- verifying that the blood-unit bar code and the patient's bar code are identical.

### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more clearly understood from the accompanying detailed description and drawings, in which same number designations are maintained throughout the figures for similar elements and in which:

Figs. 1A – 1L schematically illustrate lock-and-key apparatus for safe infusion, in accordance with a first embodiment of the present invention;

Figs. 2A – 2E schematically illustrate lock-and-key apparatus for safe infusion, in accordance with a second embodiment of the present invention; Fig. 3 schematically illustrates lock-and-key apparatus for safe infusion, in accordance with a third embodiment of the present invention;

Fig. 4 schematically illustrates lock-and-key apparatus for safe infusion, in accordance with a fourth embodiment of the present invention; and

Fig. 5 schematically illustrates lock-and-key apparatus for safe infusion, in accordance with a fifth embodiment of the present invention.

### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is now made to Figs. 1A – 1K, which together, schematically illustrate lock-and-key apparatus 22 for ensuring that an infusion is administered to a patient for whom it is intended, in accordance with a first embodiment of the invention.

Preferably, as seen in Fig. 1A, lock-and-key apparatus 22 includes proximal and distal sides 35 and 37, with respect to a user (not shown), and a first block 24 and a second block 26, arranged to be selectably joined and selectably locked together. First and second blocks 24 and 26 have a first common interface 39 between them, when they are joined. Preferably, first and second blocks 24 and 26 are hinged to each other at their distal ends.

Preferably, first block 24 further includes a channel 28, open towards first common interface 39, dividing first block 24 into a first, proximal portion 24A and a second, distal portion 24B. Additionally, second block 26 further includes a bar 30, which protrudes from second block 26 and is further arranged to be inserted into channel 28, thus forming second and third common interfaces 31 and 33, respectively between first block 24 and second block 26. A slot 32, open to proximal side 35, penetrates completely through first, proximal portion 24A, second common interface 31, bar 30, third common interface 33, and partly through second, distal portion 24B.

Preferably, as seen in Figs. 1B, 1C, and 1D, a resilient hose 36, for passing infusion liquid from an infusion bag 38 (Fig. 1D) to the patient (not shown), is placed between first block 24 and second block 26, on first common interface 39, for preventing passage of an infusion liquid when blocks 24 and 26 are locked together.

Preferably, as seen in Figs. 1E - 1H, a lock-and-key mechanism 10 includes a key 29, formed as a first plate 12, having a distal end 11, and a proximal end 13, with respect to a user, and left and right side edges 15 and 17, respectively. First plate 12 further has a hook 16, arranged at a predetermined distance from distal end 11 and side edges 15 and 17.

Additionally, lock-and-key mechanism 10 includes a lock 27, formed as a second plate 14, substantially of a same width as first plate 12, but of greater length, and having a distal end 19 and a proximal end 21, and left and right side edges 23 and 25, respectively. Second plate 14 further has a hole 18, arranged on second plate 14 at substantially the same predetermined distances from distal end 19 and side edges 23 and 25, as those of hook 16 of first plate 12. As seen in Fig. 1G, when distal end 11 of first plate 12 is arranged over distal end 19 of second plate 14, hook 16 is superimposed over hole 18.

Preferably, the predetermined distances of hook 16 and hole 18 from their respective distal end and side edges are unique to each lock-and-key mechanism 10, so that only a key 29 associated with it may be superimposed on a lock 27.

Preferably, key 29 and lock 27 are manufactured together as a single plate, which is broken along an interface 20, to form first plate 12 and second plate 14. Preferably, both plate 12 and plate 14 include holes 40, for tying them to strings to facilitate their attachment to a patient and to a test tube. Preferably, both plate 12 and plate 14 are of a proper size so that a sticker of the patient's details can be attached to each plate, for identification, in the event that, for example, a plate falls to the floor. Preferably, as seen in Fig. 1H, lock 27, containing plate 14 is attached to the test tube of the patient's blood and sent to the blood bank, preferably in a

protective envelope 49. Key 29, containing plate 12, remains with the patient, preferably, attached to the patient's person.

Preferably, as seen in Fig. 1I, apparatus 22 is locked by completely inserting lock 27, formed of second plate 14 and hole 18, into slot 32 of apparatus 22, in the direction shown by an arrow 46. Second plate 14 passes through first, proximal portion 24A of first block 24, bar 30 of second block 26, and second, distal portion 24B of first block 24, thus preventing the separation of second block 26 from first block 24. Hose 36 is thus wedged between the two blocks and allows passage therethrough of an infusion liquid from infusion bag 38 (Fig. 1D).

Preferably, as seen in Figs. 1J and 1K, apparatus 22 may be opened by inserting key 29, formed of first plate 12 and hook 16, partly through slot 32, in the direction opposite to an arrow 48, until distal end 11 (Fig. 1G) of first plate 12 overlaps with distal end 19 of second plate 14, which is completely inserted into slot 32. First plate 12 may then be used to drag second plate 14 out of slot 32, in the direction shown by arrow 48, thus unlocking apparatus 22, and releasing infusion hose 36.

Reference is now made to Fig. 1L, which schematically illustrates an alternative lock-and-key mechanism 45, in accordance with the present invention. Preferably, lock-and-key mechanism 45 includes key 29, which further includes a string arrangement 43, for attaching onto the patient's wrist (not shown). Additionally, lock-and-key mechanism 45 includes lock 27, which further includes a construction 47, for clasping onto a test tube, containing the patient's blood. Initially, lock-and-key mechanism 45 is a single unit, wherein lock 27 and key 29 are attached along seam 20, and lock 27 and construction 47 are attached along a seam 41. Preferably, after the blood sample is taken, key 29 is separated from lock 27 and tied to the patient's body, preferably, using string arrangement 43. Preferably, lock 27 and construction 47 are sent to the blood bank, preferably in protective envelope 49 (Fig. 1H). In the blood bank, lock 27 is separated from construction 47, along seam 41, and is used to lock apparatus 22, as has been described in conjunction with Figs. 1A – 1K.

In accordance with the first embodiment of the present invention, the method of using apparatus 22 and lock-and-key mechanism 10 for the infusion of blood, is as follows:

1. At the time of blood sampling, in addition to the procedure delineated by the regulations of the Ministry of Health, the performing doctor will break out a unit of lock-and-key mechanism 10, preferably, already containing stickers of the patient's details, and attach lock 27 to the test tube of the patient's blood, which is to be sent to

the blood bank, preferably in protective envelope 49 (Fig. 1H). The doctor will leave key 29 with the patient, for example, by attaching it to the patient's person.

2. In the blood bank, the blood units will be prepared, in accordance with a blood-order form attached to the test tube, and locked into apparatus 22, as has been described hereinabove. Thus only the patient who has the correct key 29 will be able to unlock apparatus 22 and receive the infusion liquids.

In alternate embodiments of the present invention, lock 27 may include a recessed portion 18 rather than hole 18 (Fig. 1G). Additionally, key 29 may include a protrusion 16 rather than hook 16.

In alternate embodiments of the present invention, an edge 339 of blood bag 38 (Fig. 1D) may be inserted into apparatus 22 rather than hose 36.

In alternate embodiments of the present invention, apparatus 22 or first block 24 may not include channel 28. Rather, bar 30 extends over first block 24, overlapping it at proximal end 35, forming only second interface 31. Thus, slot 32 completely penetrates bar 30 and second interface 31, and partially penetrates first block 24.

Reference is now made to Figs. 2A – 2E, which together, schematically illustrate lock-and-key apparatus 50 for ensuring that an infusion is administered to a patient for whom it is intended, in accordance with a second embodiment of the present invention. As shown in Figures 2A-2E, apparatus 50 can be electronically controlled and computer-controlled for preventing unauthorized access to blood bag 38.

Preferably, as seen in Figs. 2A and 2B, lock-and-key apparatus 50 includes a first block 52 and a second block 54, which are arranged to be selectably joined and selectably locked, along a common interface 65. First block 52 and second block 54 are further arranged to accept a resilient portion of the infusion-bag administration system, for example, resilient infusion hose 36, between them. Preferably, first block 52 and second block 54 are hinged to each other at one side.

Apparatus 50 further includes processing and memory units (not shown), and an on/off switch 60. Apparatus 50 may be powered by a battery (not shown), or may be connected to a grid (not shown). Preferably, apparatus 50 is a stand-alone unit, however, a jack 62 is provided for downloading data accumulated in apparatus 50 to a data bank of a computer 80 (Fig. 2E). Computer 80 is also geared towards being used as a processing unit 80 in communication with a signal reader 56 and with lock 67, for processing a patient's signal

information from signal reader 56 and for selectably opening the lock based on the patient's signal information.

Additionally, apparatus 50 includes a lock 67, which includes a first locking component 64 and a second locking component 66, arranged to lock together, electronically, preferably with a switch 69, and arranged to open electronically, upon a command from the processing unit 80. The processing unit 80 is programmed to issue a command to unlock apparatus 50 only upon receiving an electronic key, formed of the patient's signals, for example, the patient's bar code signals, and preferably further including signals indicating the presence of a doctor and a nurse on signal scanner 56.

As seen in Fig. 2C, apparatus 50 further includes a control panel 58, which includes first, second, and third indicators 70, 72 and 74, respectively. Indicators 70, 72, and 74 may be, for example, light indicators. Alternatively, they may be written-message indicators or vocal indicators.

Additionally, apparatus 50 includes a hand-held scanner 56, arranged for reading bar codes of patients, doctors and nurses. Apparatus 50 is programmed at the blood bank, as will be described hereinbelow, to unlock only when the bar code on the patient's person is the same as the bar code on the blood unit and preferably, when bar codes of a doctor and a nurse are scanned by scanner 56, indicating their presence.

As seen in Fig. 2D, when three indicators 70, 72, and 74 are on, apparatus 50 unlocks and releases hose 36.

In accordance with the second embodiment of the present invention, the method of using apparatus 50, for the infusion of blood, is as follows:

1. At the blood bank, the blood is prepared and a resilient portion of the infusion-bag administration system, for example, resilient infusion hose 36, is arranged between first block 52 and second block 54. Apparatus 50 is then locked and programmed to open electronically, upon receiving a bar-code signal of the patient, whose bar code was on the sampled-blood test tube, and preferably, bar codes indicating the presence of a doctor and a nurse. Apparatus 50 may be programmed via computer 80 (Fig. 2E) or may have switches or keys for programming.
2. Prior to blood infusion, in addition to the blood-infusion protocol delineated by the Ministry of Health, requiring visual examination and visual comparison of the patient's details, the doctor and the nurse will scan the patient's bar code, on his identity band, on his person, and the bar code on the blood bag. When the bar codes agree, first

indicator 70 will come on. The doctor will then scan his own bar code, to register himself as the performing doctor and to indicate his presence, and second indicator 72 will come on. The nurse will then scan the nurse's bar code to register the nurse as the performing nurse and to indicate his presence, and third indicator 74 will come on. Once the three indicators come on, apparatus 50 will open electronically, allowing blood infusion to proceed.

Preferably, as seen in Fig. 2E, after the blood infusion, apparatus 50 is returned to the blood bank and the infusion scanning information is downloaded to blood bank computer 80 for record.

Reference is now made to Fig. 3, which schematically illustrates lock-and-key apparatus 88 for ensuring that an infusion is administered to a patient for whom it is intended, in accordance with a third embodiment of the invention.

In essence, apparatus 88 includes apparatus 50, described hereinabove. Apparatus 88 further includes a hanging device 84, arranged on apparatus 50 and a receiving device 86, arranged on a blood infusion bag 82, for hanging apparatus 50 thereon. The purpose of devices 84 and 86 is to provide a facile arrangement for combining infusion bag 82, apparatus 50 and hose 36 (Fig. 2B), locked therein.

In alternate embodiments of the present invention, lock and key apparatus 50 is not used. Rather, bar-code scanner 56 (Fig. 2C) is preferably, a stand-alone, hand-held, bar-code scanner, having control panel 58, for signal output, preferably including at least one indicator, such as indicator 70. Indicator 70 may be, for example, a light indicator. Alternatively, indicator 70 may be a written message or a vocal signal.

1. At the time of blood sampling, in addition to the procedure delineated by the regulations of the Ministry of Health, the performing doctor will scan the patient's bar code, on his identity band, on his person, and the bar code on the test tube for blood sampling. The doctor will sample blood only when indicator 70 signals agreement between the two scans.
2. Prior to blood infusion, in addition to the blood-infusion protocol delineated by the Ministry of Health, requiring visual examination and visual comparison of the patient's details, both the doctor and the nurse, each in turn, will scan the patient's bar code, on his identity band, on his person, and the bar code on the blood bag. Blood will be administered only when indicator 70 signals agreement between the two scans.

Reference is now made to Fig. 4, which schematically illustrates a clamp 90, for ensuring that an infusion is administered to a patient for whom it is intended, in accordance with a fourth embodiment of the present invention. Preferably, clamp 90 is formed of two bars 92, hinged at one end, and arranged to clamp hose 36 between them. Bars 92 include holes 94, through which a lock 27 may be inserted. Preferably, lock 27 is forwarded to the blood bank, together with the test tube containing the patient's blood, preferably in protective envelope 49, as has been described in conjunction with Fig. 1H. Preferably, key 29, associated with lock 27, remains with the patient, for example, attached to the patient's wrist, preferably, with string arrangement 43. Lock 27 and key 29 may be a mechanical or electronic lock and key, for preventing liquid displacement in hose 36.

In alternate embodiments of the present invention, clamp 90 may be any clamping device, arranged to be locked and provided with a key including, but not limited to, mechanical, electronic and electromechanical locks as shown in Figures 1A-5.

Reference is now made to Fig. 5, which schematically illustrates a container 100, such as a box 100, for ensuring that an infusion is administered to a patient for whom it is intended, in accordance with a fifth embodiment of the present invention. Preferably, box 100 is arranged for containing blood bag 38, locked with key 27. Preferably, lock 27 is forwarded to the blood bank, together with the test tube containing the patient's blood, preferably in protective envelope 49, as has been described in conjunction with Fig. 1H. Preferably, key 29, associated with lock 27, remains with the patient, for example, attached to the patient's wrist, preferably, with string arrangement 43. Preferably, lock 27 is an electromagnetic lock, arranged to read an electromagnetic card or another electromagnetic device, and key 29 is the electromagnetic device. Alternatively, lock 27 and key 29 are physical lock and key.

In alternate embodiments of the present invention, container 100 may be any container, arranged to be locked and provided with a key. For example, container 100 may be cylindrical in shape.

It will be appreciated by persons skilled in the art, that the scope of the present invention is not limited by what has been specifically shown and described hereinabove, merely by way of example. Rather, the scope of the invention is limited solely by the claims, which follow.

## CLAIMS

1. For use with an infusion-bag administration system, lock-and-key apparatus for ensuring that an infusion is administered to a correct patient, which includes:

proximal and distal sides with respect to a user;

first and second blocks, arranged to be selectably joined and selectably locked together, and having a first common interface between them, when they are joined; and

a lock-and-key mechanism which includes:

a lock, in communication with said first and second blocks, for selectably locking them together; and

a key, located with the patient to whom the infusion is intended, for unlocking said lock,

wherein, when a resilient portion of the infusion-bag administration system is arranged between said first and second blocks, on said first interface, the locking of said first and second blocks together will prevent passage of the infusion liquid.

2. Apparatus according to claim 1, wherein said first and second blocks are physically attached to one another with at least one hinge.

3. Apparatus according to claim 1, wherein said lock includes:

a first plate, having distal and proximal ends, with respect to a user, and side edges; and

a recessed portion, arranged on said first plate at predetermined distances from said distal end and side edges,

wherein said key includes:

a second plate substantially of a same width as said first plate, but of greater length, and also having distal and proximal ends, and side edges; and

a protrusion, arranged on said second plate at substantially the same predetermined distances from said distal end and side edges, as those of said recessed portion of said first plate, so as to be superimposed on said recessed portion,

wherein said predetermined distances of said recessed portion and protrusion from said distal end and side edges are unique to each lock and key, so that only a key associated with it may be superimposed on a lock,



wherein said second block includes a bar, protruding from it and arranged to cover a side of said first block, when said first and second blocks are joined, and further including a slot which penetrates fully through said bar of said second block and partly through said first block, from said proximal side,

wherein when said first and second blocks are joined together and said first plate is fully inserted into said slot, said first and second blocks are locked together,

and wherein when said second plate, which is of greater length than said first plate, is partially inserted into said slot, locking its protrusion against said recessed portion of said first plate, and dragging said first plate out of said slot, said first and second blocks are unlocked.

4. Apparatus according to claim 3, wherein said recessed portion is a through hole.

5. Apparatus according to claim 3, wherein said protrusion is shaped as a hook.

6. Apparatus according to claim 3,

wherein said first block further includes a channel, open towards said first common interface, and dividing said first block into a first, proximal portion and a second, distal portion,

wherein said bar, protruding from said second block, is further arranged to be inserted into said channel, thus forming second and third common interfaces between said first and second blocks,

and wherein said slot penetrates from said proximal side of said apparatus, completely through said first, proximal portion of said first block, said second common interface, said bar of said second block, said third common interface, and partly penetrates through said second, distal portion of said first block.

7. Apparatus according to claim 3, wherein said first and second plates are disposable.

8. Apparatus according to claim 1, wherein said lock is electronically controlled, said key includes patient's signal information, and said apparatus further includes:

a signal reader for reading said patient's signal information; and

a processing unit, in communication with said signal reader and with said lock, for processing said patient's signal information from said signal reader and for selectably opening said lock based on said patient's signal information.

9. Apparatus according to claim 8, wherein said key further includes signal information of a medical doctor and of a nurse who are administering the infusion.

10. Apparatus according to claim 8, wherein the patient's signal information is a bar code, physically attached to his person, and wherein said signal reader is a bar-code scanner, arranged to read said bar code.

11. Apparatus according to claim 8, wherein the patient's signal information is the patient's palm print, and wherein said signal reader is a palm-print reader.

12. Apparatus according to claim 8, wherein the patient's signal information is the patient's fingerprint, and wherein said signal reader is a fingerprint reader.

13. Apparatus according to claim 1, wherein said apparatus is physically hung from an infusion bag containing the infusion liquid for the patient, and wherein when said apparatus is unlocked, the infusion liquid flows freely and can be administered to the patient.

14. Apparatus according to claim 1, wherein at least one of said first and second blocks is hollow, forming a cavity, and wherein the infusion bag is contained in said cavity.

15. Apparatus according to claim 1, wherein said resilient portion of the infusion-bag administration system, through which the infusion liquid exits, is a resilient hose, connected to the infusion bag.

16. Apparatus according to claim 1, wherein said resilient portion of the infusion-bag administration system, through which the infusion liquid exits, is an edge of the infusion bag.

17. Apparatus according to claim 1, wherein the infusion liquid is blood.

18. A method for ensuring that an infusion is administered to a correct patient, which includes the steps of:

at the location where the infusion liquid is prepared, locking the infusion liquid with a lock, whose key is uniquely with the patient; and

by the patient, unlocking the infusion liquid with the patient's key.

19. A method according to claim 18, wherein said step of locking includes locking with a physical lock, and said step of unlocking includes unlocking with a physical key.

20. A method according to claim 18, wherein said step of locking includes locking electronically.

21. A method according to claim 20, wherein said step of unlocking includes unlocking with an electromagnetic device.

22. A method according to claim 20, wherein said step of unlocking includes unlocking electronically, which includes a step of reading in the patient's key, formed of the patient's signals.

23. A method according to claim 22, wherein said step of reading in the patient's key, formed of the patient's signals, includes reading in a bar code, attached to the patient.

24. A method according to claim 22, wherein said step of reading in the patient's key, formed of the patient's signals, includes reading in the patient's palm print.

25. A method according to claim 22, wherein said step of reading in the patient's key, formed of the patient's signals, includes reading in the patient's fingerprints.

26. A method according to claim 22, wherein said step of reading in the patient's key, formed of the patient's signals, further includes reading in a doctor's signals and a nurse's signals, for indicating their presence, and for registering their identity.

27. A method according to claim 18, wherein said step of locking the infusion liquid with a lock further includes the steps of:
- clamping the infusion liquid exit path with a clamp; and
  - locking the clamp, to prevent passage of the infusion liquid.
28. A method according to claim 18, wherein said step of locking the infusion liquid with a lock further includes the steps of:
- placing the infusion liquid in a container; and
  - locking the container.
29. A method for ensuring that a blood sample is marked correctly, which includes:
- employing a bar-code scanner;
  - scanning the bar code on the test tube into which the blood sample is to be drawn;
  - scanning the bar code on the band of the patient from whom the blood sample is to be drawn; and
  - verifying that the test-tube bar code and the patient's bar code are identical.
30. A method for ensuring that an infusion is administered to a correct patient, which includes:
- employing a bar-code scanner;
  - scanning the bar code on the blood-unit bag;
  - scanning the bar code on the band of the patient who is to receive the blood; and
  - verifying that the blood-unit bar code and the patient's bar code are identical.
31. A method according to claim 18, wherein the infusion liquid is blood, and the location where the infusion liquid is prepared is a blood bank.
32. A lock-and-key apparatus for ensuring that an infusion is administered to a correct patient, comprising:
- (a) a proximal side and a distal side with respect to a user;
  - (b) a first block and a second block, arranged to be selectably joined and selectably locked together, and having a first common interface between them, when they are joined; and
  - (c) a lock-and-key mechanism including:

(i) a lock, in communication with said first and second blocks, for selectably locking them together; and

(ii) a key, located with the patient to whom the infusion is intended, for unlocking said lock and wherein, when passage of liquid in a resilient portion of the infusion-bag administration system is substantially prevented, occasioning on said resilient portion being situated between said first and second blocks.

33. The apparatus for ensuring that an infusion is administered to a correct patient of claim 32, further comprising a signal reader for verifying the identity of the patient prior to administering the infusion.

34. The apparatus for ensuring that an infusion is administered to a correct patient of claim 32, further comprising a first locking component for locking said resilient portion electronically.

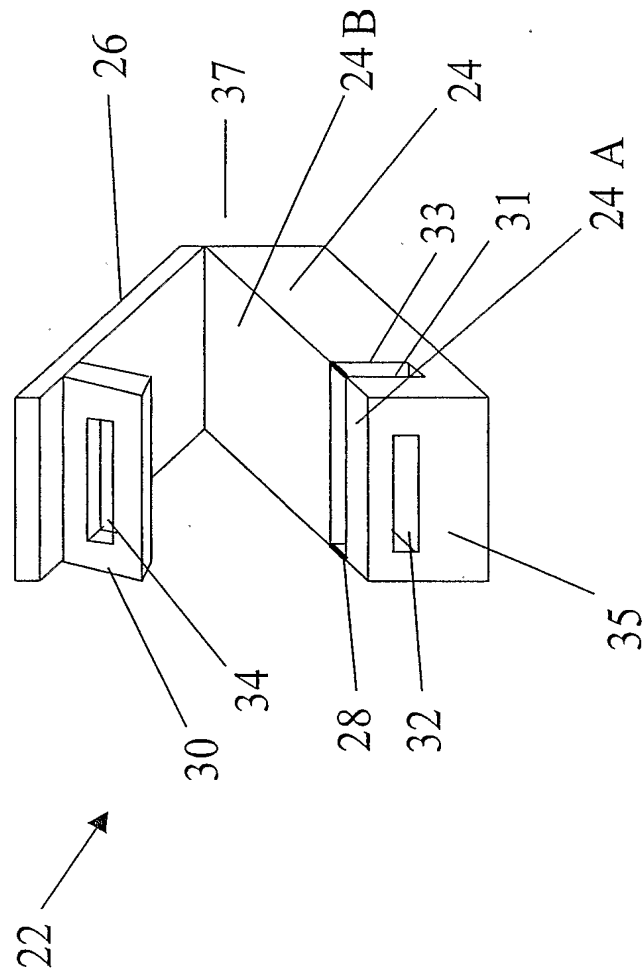
35. The apparatus for ensuring that an infusion is administered to a correct patient of claim 32, further comprising a first locking component and a second locking component, arranged to lock together, electronically.

36. The apparatus for ensuring that an infusion is administered to a correct patient of claim 32, wherein said lock is mechanical, electronic or electro-mechanical.

37. The apparatus for ensuring that an infusion is administered to a correct patient of claim 36, further comprising a bar-code scanner for identifying the identity of the individual administering the infusion.

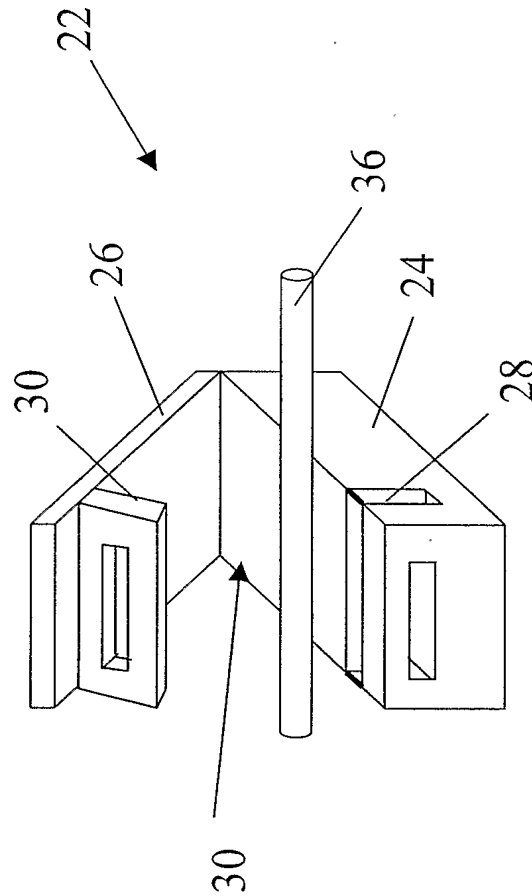
38. The apparatus for ensuring that an infusion is administered to a correct patient of claim 32, wherein said key is mechanical, electronic or electro-mechanical.

**Fig. 1A**



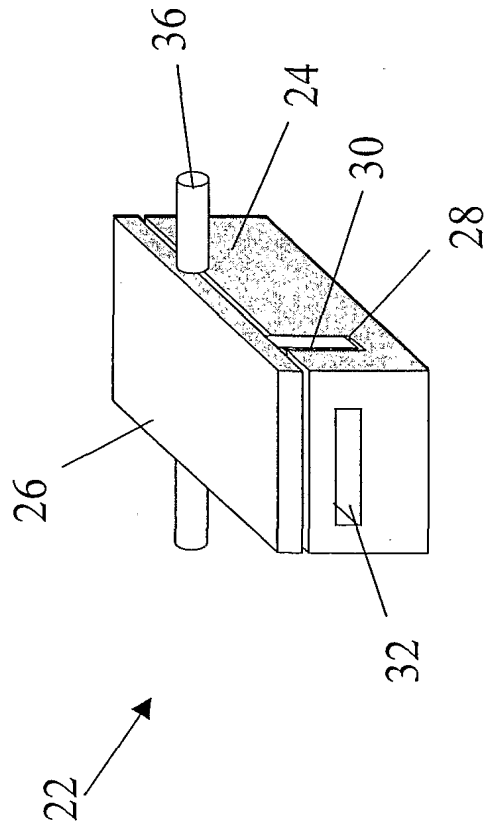
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**Fig. 1B**



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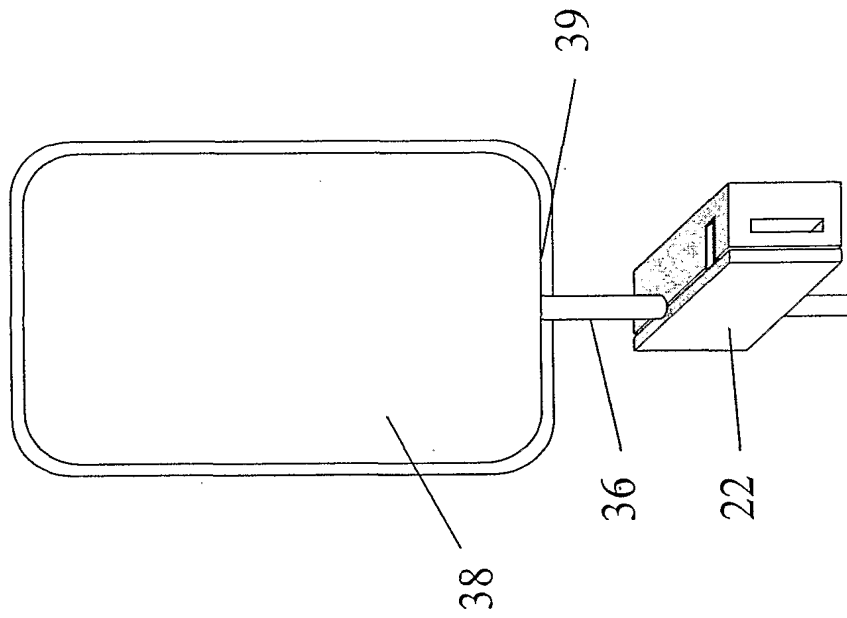
Fig. 1C





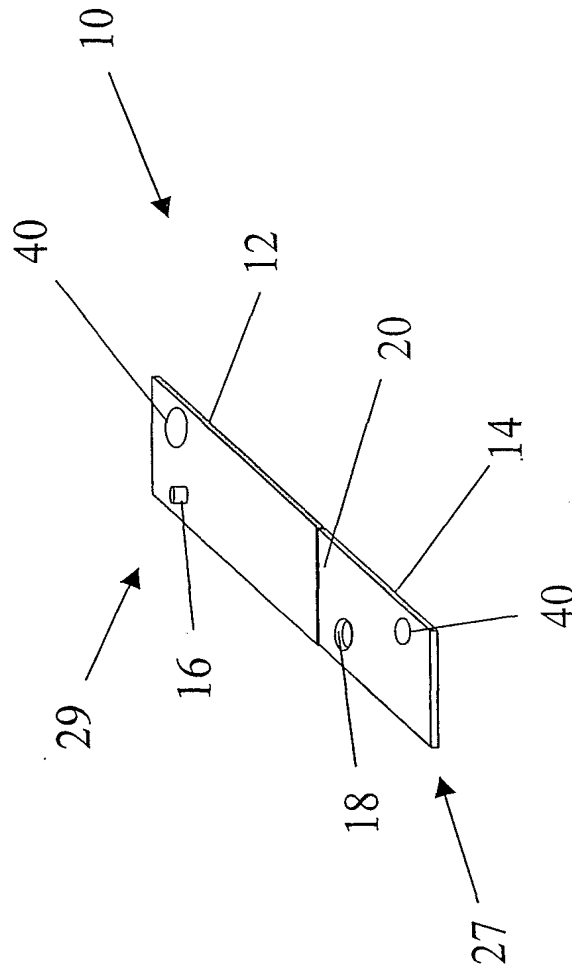
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Fig. 1D



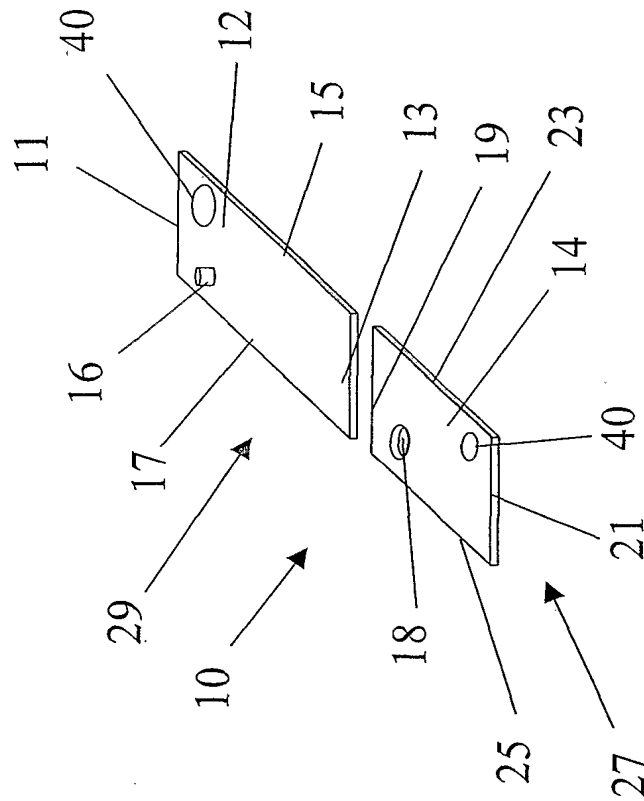
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Fig. 1E



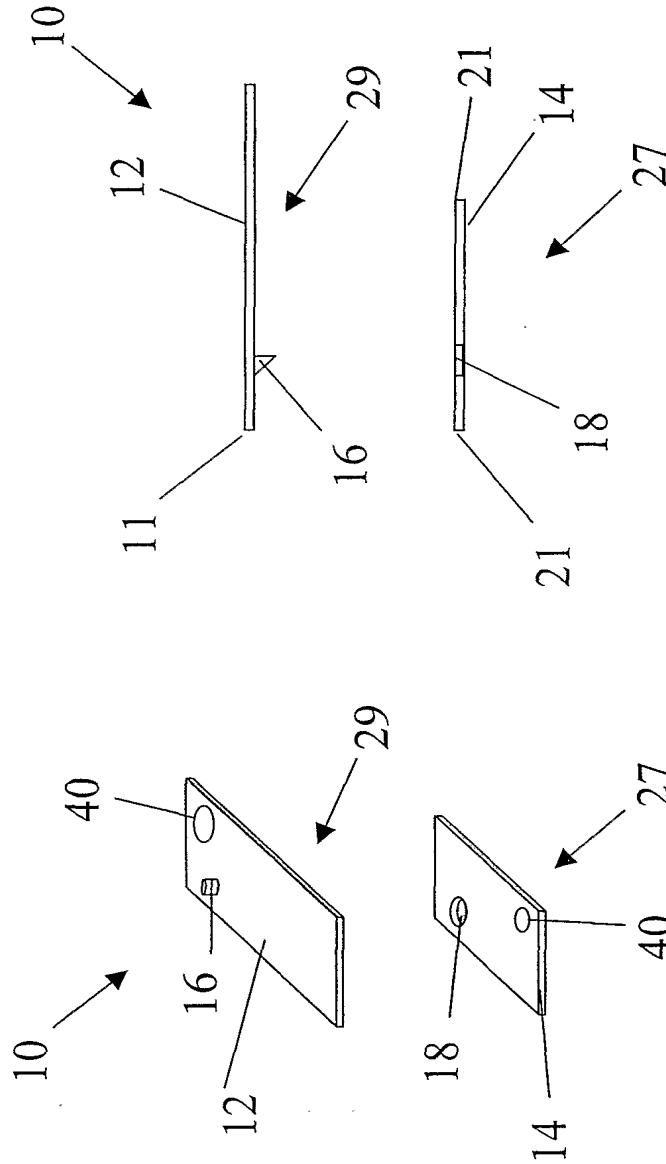
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**Fig. 1F**



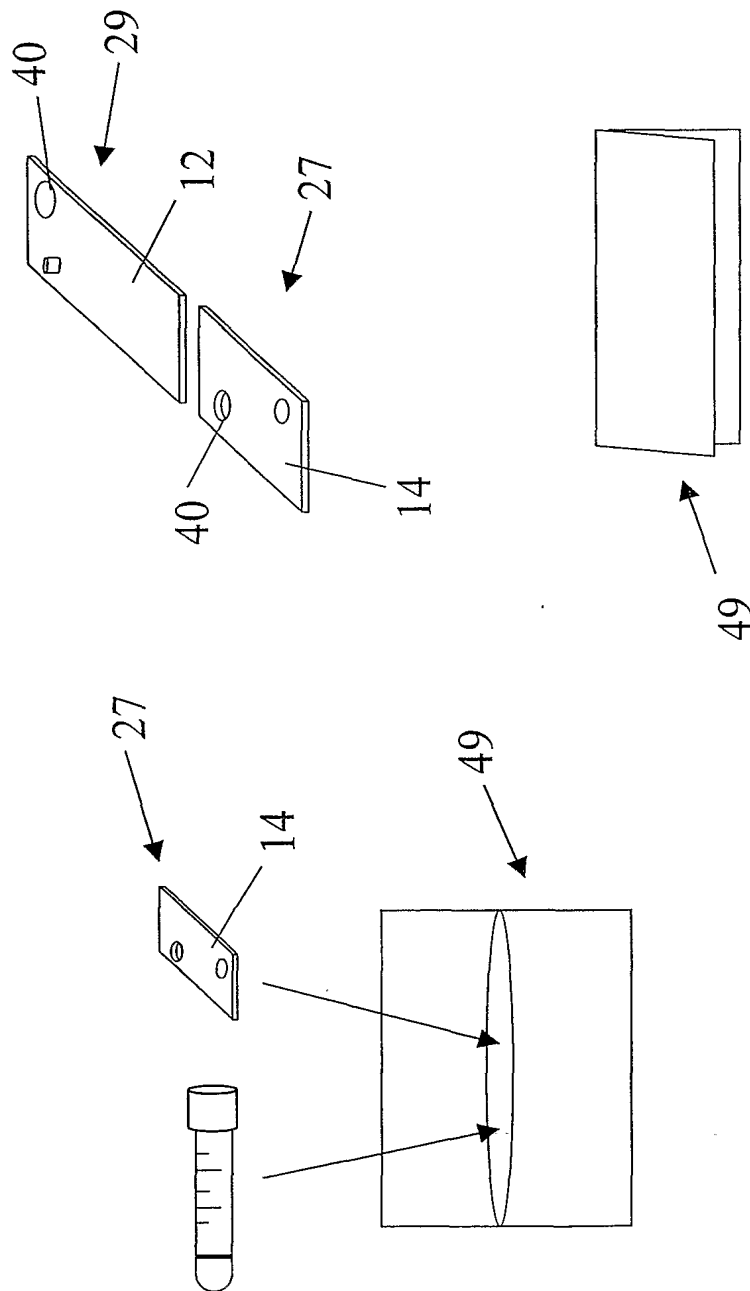
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Fig. 1G



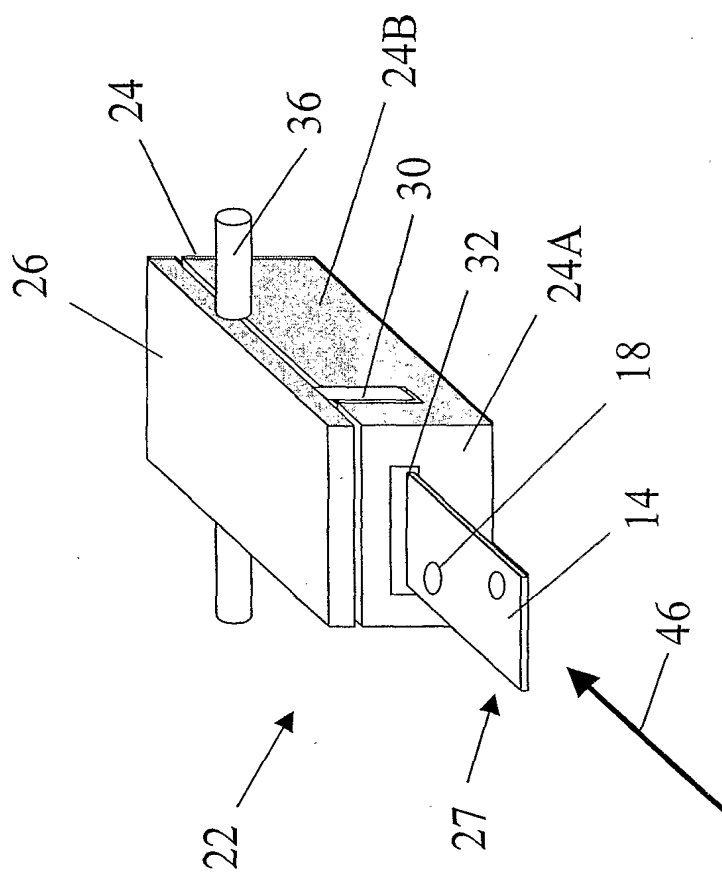
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Fig. 1H



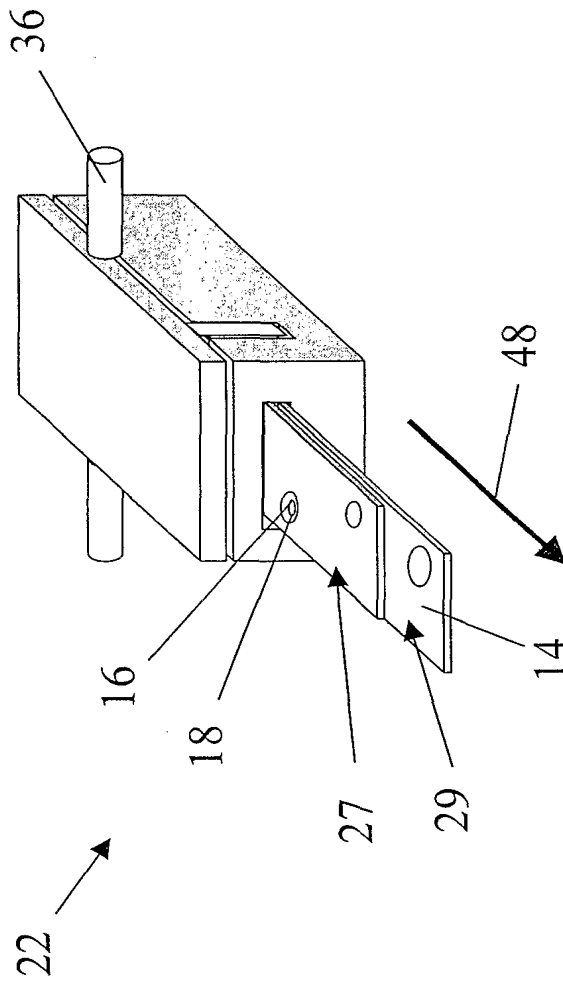
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**Fig. 11**

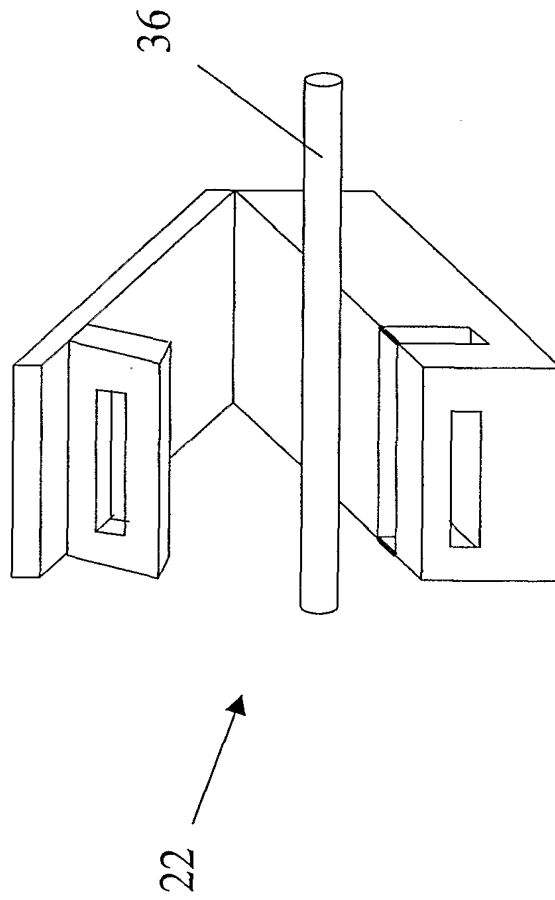


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Fig. 1J



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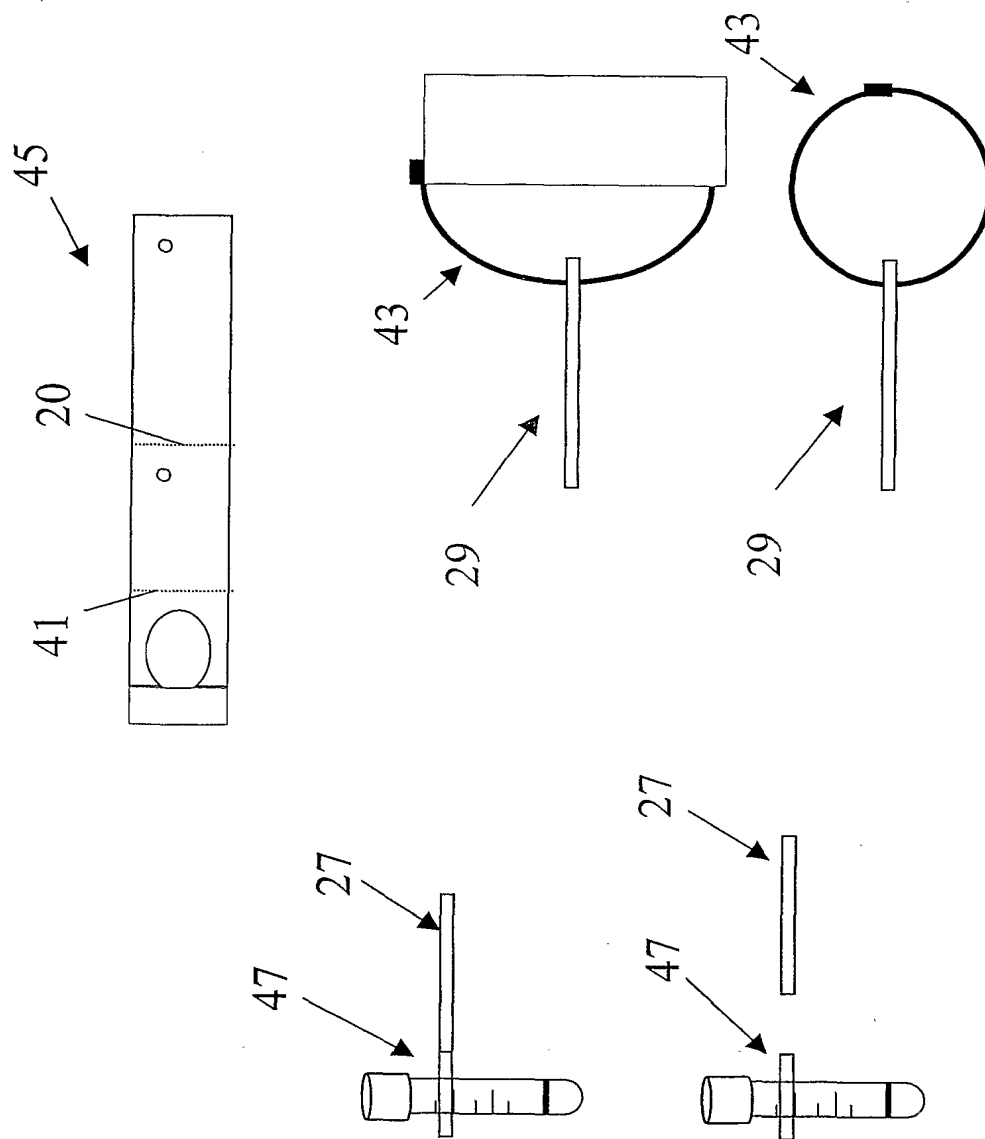


**Fig. 1K**



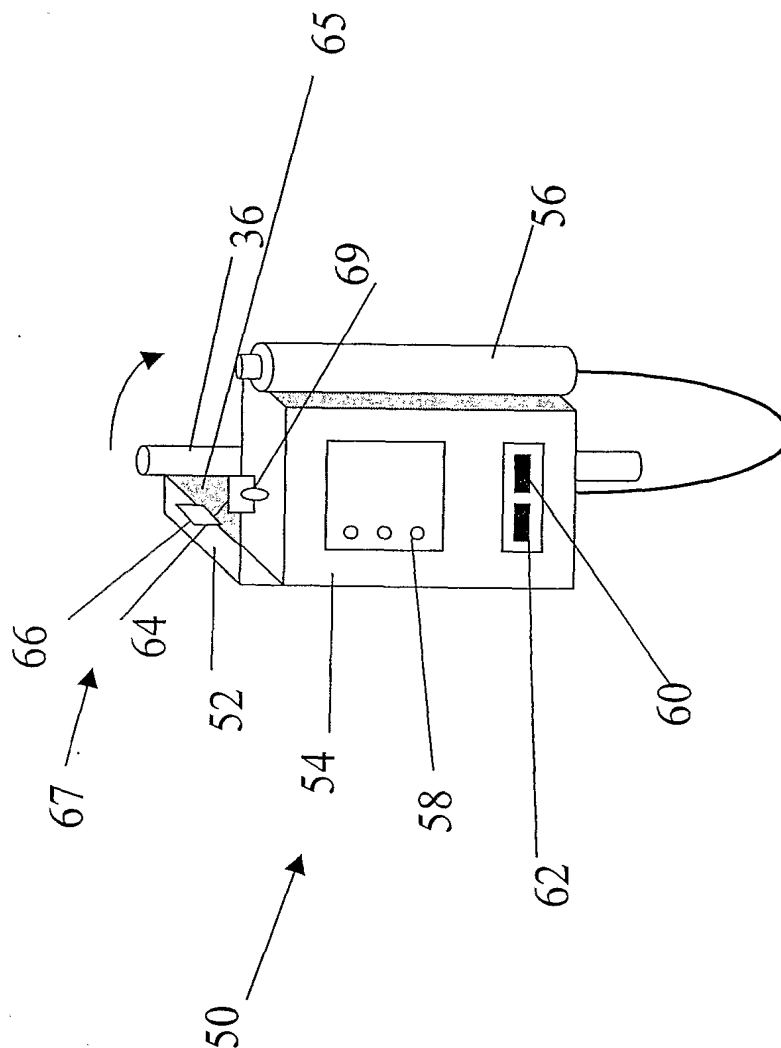
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Fig. 1L



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**Fig. 2A**



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Fig. 2B

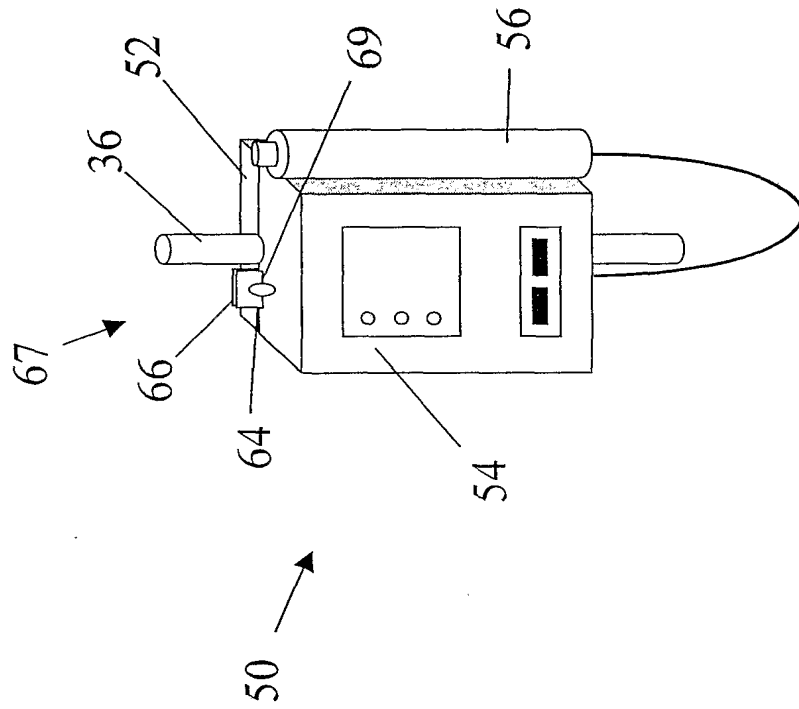
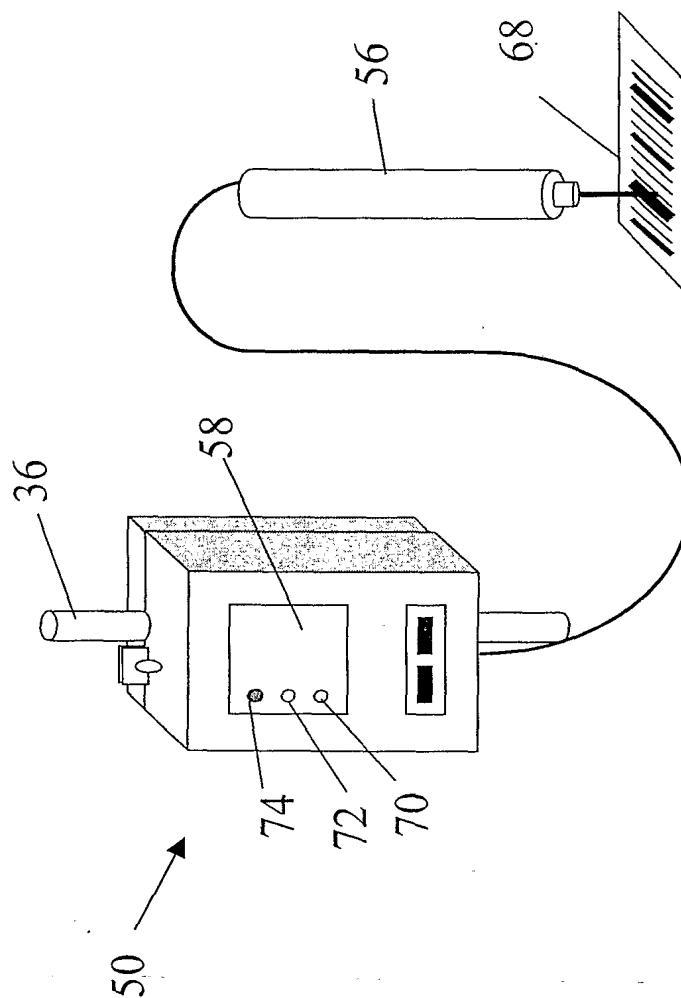


Fig. 2C



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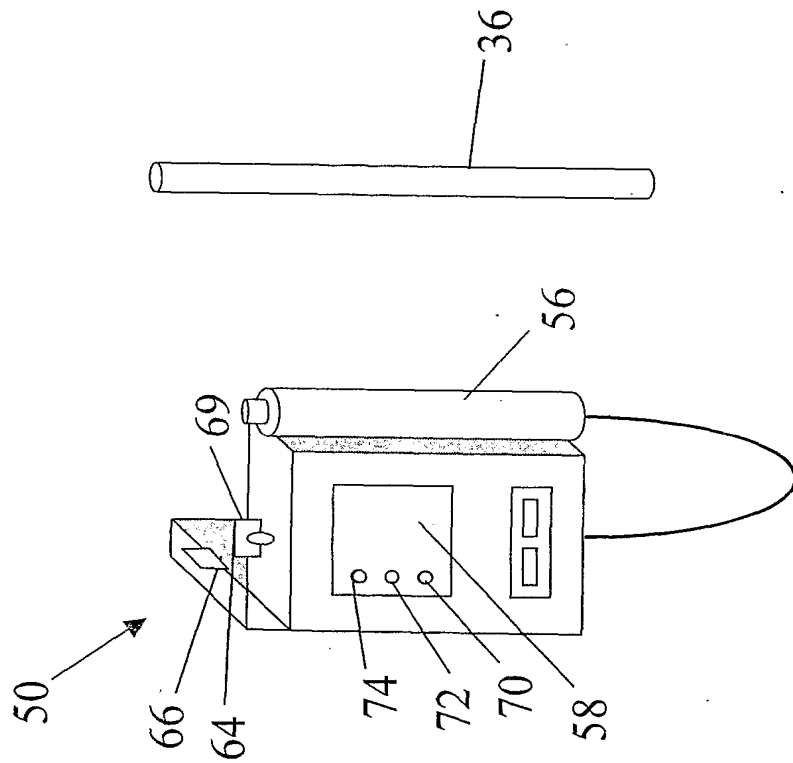


Fig. 2D

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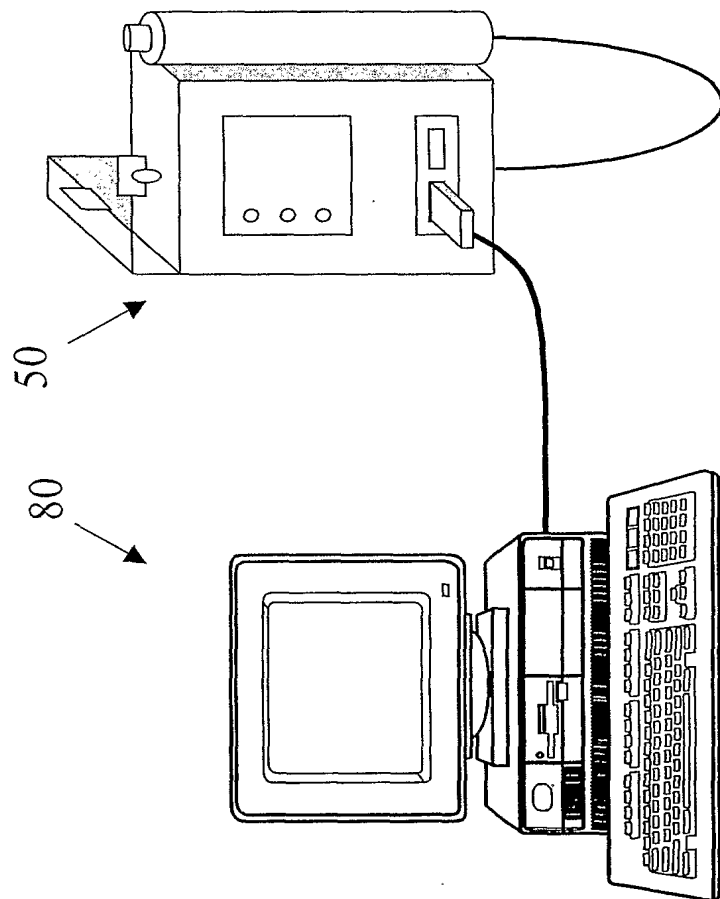


Fig. 2E

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Fig. 3

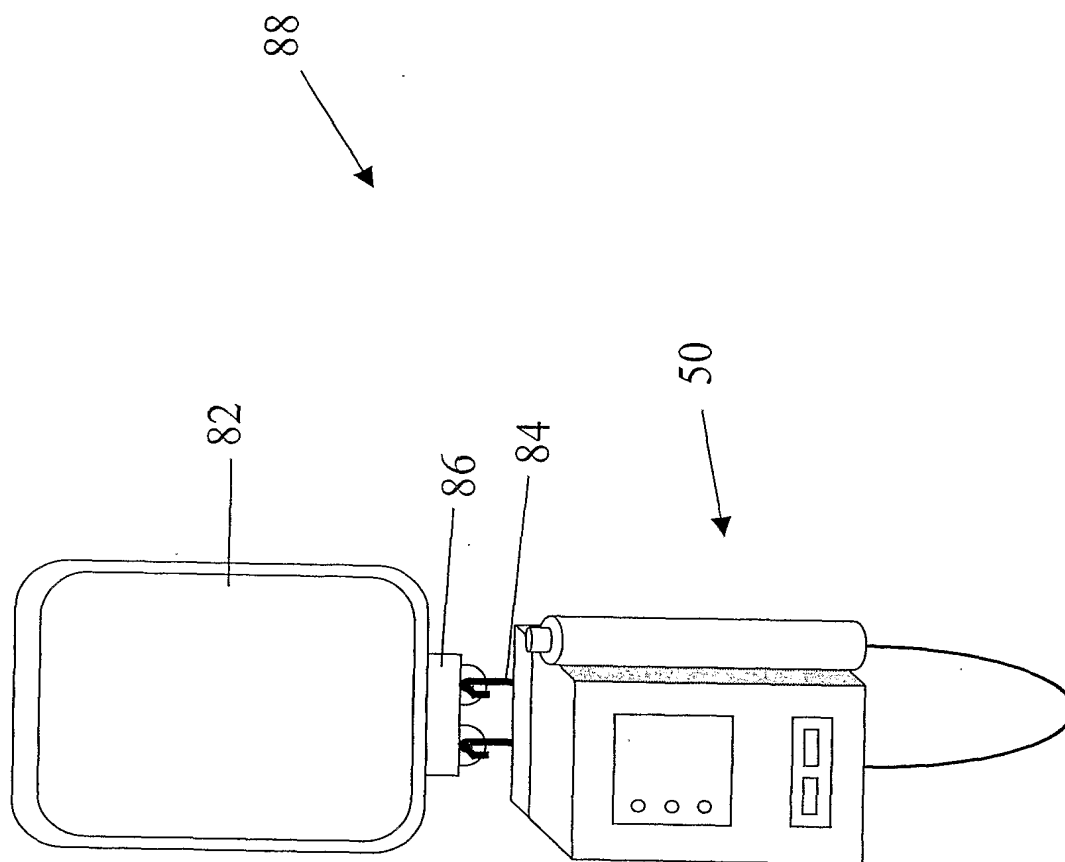


Fig. 4

